

may for good cause shown refer the petition to the appropriate classification panel for its review and recommendation whether to approve or deny the petition.

(4) Within 90 days after the date the petition is referred to the panel, following the review procedures set forth in § 860.84(c) for the original classification of an “old” device, the panel submits to the Commissioner its recommendation containing the information set forth in § 860.84(d). A panel recommendation is regarded as preliminary until the Commissioner has reviewed it, discussed it with the panel, if appropriate, and developed a proposed reclassification order. Preliminary panel recommendations are filed in the Dockets Management Branch upon receipt and are available to the public upon request.

(5) The panel recommendation is published in the FEDERAL REGISTER as soon as practicable and interested persons are provided an opportunity to comment on the recommendation.

(6) Within 90 days after the panel’s recommendation is received (and no more than 210 days after the date the petition was filed), the Commissioner denies or approves the petition by order in the form of a letter to the petitioner. If the Commissioner approves the petition, the order will classify the device into class I or class II in accordance with the criteria set forth in § 860.3(c) and subject to the applicable requirements of § 860.93, relating to the classification of implants, life-supporting or life-sustaining devices, and § 860.95, relating to exemptions from certain requirements of the act.

(7) Within a reasonable time after issuance of an order under this section, the Commissioner announces the order by notice published in the FEDERAL REGISTER.

[43 FR 32993, July 28, 1978, as amended at 57 FR 58404, Dec. 10, 1992]

§ 860.136 Procedures for transitional products under section 520(l) of the act.

(a) Section 520(l)(2) of the act applies to reclassification proceedings initiated by a manufacturer or importer for reclassification of a device currently in class III by operation of section

520(l)(1) of the act. This section applies only to devices that the Food and Drug Administration regarded as “new drugs” before May 28, 1976.

(b) The procedures for effecting reclassification under section 520(l) are as follows:

(1) The manufacturer or importer of the device files a petition for reclassification of the device in accordance with § 860.123.

(2) Within 30 days after the petition is filed, the Commissioner notifies the petitioner of any deficiencies in the petition that prevent the Commissioner from making a decision on it, allowing the petitioner to supplement a deficient petition. Within 30 days after any supplemental material is received, the Commissioner notifies the petitioner whether the petition, as supplemented, is adequate for review.

(3) The Commissioner provides the petitioner an opportunity for a regulatory hearing conducted in accordance with Part 16 of this chapter.

(4) The Commissioner consults with the appropriate classification panel with regard to the petition in accordance with § 860.125.

(5) Within 180 days after the petition is filed (where the Commissioner has determined it to be adequate for review), the Commissioner, by order in the form of a letter to the petitioner, either denies the petition or classifies the device into class I or class II in accordance with the criteria set forth in § 860.3(c).

(6) Within a reasonable time after issuance of an order under this section, the Commissioner announces the order by notice published in the FEDERAL REGISTER.

PART 861—PROCEDURES FOR PERFORMANCE STANDARDS DEVELOPMENT

Subpart A—General

Sec.

861.1 Purpose and scope.

861.5 Statement of policy.

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